

The Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application.

Listing of claims:

1. (Previously presented) A method of manufacturing a water-insoluble azole antifungal active agent-oral dosage form, said method comprising the steps of:
 - providing a single phase working solution comprising a water-insoluble azole antifungal active agent, water, a water-soluble polymer and a solvent, said solvent selected from the group consisting of alcohol, acetone, and mixtures thereof;
 - providing core particles formed from a pharmaceutically acceptable material;
 - combining said working solution with said particles to produce water-insoluble azole antifungal active agent-coated particles;
 - drying said water-insoluble azole antifungal active agent -coated particles;
 - and
 - forming said dried particles into an oral dosage form;
 - wherein said working solution is essentially free of methylene chloride, and said oral dosage form is essentially free of methylene chloride.
2. (Previously presented) The method of claim 1, further comprising the step of adjusting the pH of said working solution to solubilize said water-insoluble azole

antifungal active agent prior to said providing step.

3. (Previously presented) The method of claim 1, wherein said working solution further comprises a surfactant.
4. (Previously presented) The method according to claim 1, wherein said single phase working solution has a viscosity of from 10 – 2000 mPa.s during said combining step.
5. (Previously presented) The method according to claim 1, wherein the ratio of water-insoluble azole antifungal active agent-to water-soluble polymer in said working solution is from 1:0.5 to 1:20 on a weight: weight basis.
6. (Previously presented) The method according to claim 1, wherein the ratio of solvent to water in said working solution is from 50:50 to 95:5 on a weight: weight basis.
7. (Previously presented) The method according to claim 1, wherein said water-insoluble azole antifungal active agent comprises active agent in amorphous form.
8. (Canceled)

9. (Withdrawn) The method of claim 1, wherein said active agent is selected from the group consisting of saquinavir, cyclosporine and paclitaxel.
10. (Withdrawn) The method of claim 1, wherein said active agent is saquinavir.
11. (Withdrawn) The method of claim 1, wherein said active agent is cyclosporine.
12. (Withdrawn) The method of claim 1, wherein said active agent is paclitaxel.
13. (Withdrawn) The method of claim 1, wherein said active agent is subject to the proviso that sparingly water soluble antifungal agents are excluded there from.
14. (Canceled)
15. (Previously presented) The method according to claim 1, wherein said alcohol is selected from the group consisting of methanol, ethanol, propanol, butanol, and mixtures thereof.
16. (Previously presented) The method according to claim 1, wherein said water-soluble polymer is selected from the group consisting of hydroxypropyl methylcellulose, methacrylate, hydroxypropylcellulose, polyvinylpyrrolidones, dextrins and maltodextrins.

17. (Previously presented) The method according to claim 3, wherein said surfactant is selected from the group consisting of Sodium Lauryl Sulfate; Polysorbate 20, 40, 60, 80; Polyoxyethylene glycolated natural or hydrogenated vegetable oils such as polyoxyethylene glycolated natural or hydrogenated castor oils (Cremophor ®), Poloxamer, Polyoxyethylen 50 Stearate, Propylene Glycol Monostearate, Sorbitan Monolaurate, Sorbitan Monooleate, Sorbitan Monopalmitate, and Sorbitan Monostearate.
18. (Previously presented) The method according to claim 1, wherein said core particles comprise microcrystalline cellulose spheres.
19. (Previously presented) The method according to claim 1, wherein said core particles comprise mannitol spheres.
20. (Previously presented) The method according to claim 1, wherein said core particles are from 100 to 1000 micrometers in diameter.
21. (Canceled)
22. (Previously presented) The method of claim 1, wherein said drying step is followed by the step of coating said spheres with an external coating.

23. (Previously presented) A pharmaceutically acceptable particle produced by the process of claim 1.
24. (Withdrawn) The particle of claim 23, wherein said active agent is selected from the group consisting of saquinavir, cyclosporine and paclitaxel.
25. (Withdrawn) The particle of claim 23, wherein said active agent is saquinavir.
26. (Withdrawn) The particle of claim 23, wherein said active agent is cyclosporine.
27. (Withdrawn) The particle of claim 23, wherein said active agent is paclitaxel.
28. (Withdrawn) A pharmaceutically acceptable particle comprising:
a central rounded or spherical core comprised of a core material; and a coating film formed on said core, said coating film comprising a water-soluble polymer and active agent; with said particle comprising, by weight, from 5 to 40 percent active agent; from 10 to 80 percent particle core material; and from 10 to 80 percent water-soluble polymer;
and with said particle containing less than 200 ppm methylene chloride.
29. (Withdrawn) The particle according to claim 28, wherein said active agent comprises active agent in amorphous form.

30. (Withdrawn) The particle according to claim 28, wherein said active agent is selected from the group consisting of protease inhibitors, proton pump inhibitors, oligopeptides, statins, antibiotics, antifungals and antineoplastics.
31. (Withdrawn) The particle according to claim 28, wherein said core material comprises microcrystalline cellulose.
32. (Withdrawn) The particle according to claim 28, wherein said water soluble polymer is selected from the group consisting of hydroxypropyl methylcellulose, polymethacrylate, hydroxypropylcellulose, polyvinylpyrrolidones, dextrins and maltodextrins.
33. (Withdrawn) The particle according to claim 28, wherein said particle further comprises an external coating formed on said coating film.
34. (Withdrawn) An active agent oral dosage form comprising a pharmaceutically effective amount of particles according to claim 28.
35. (Withdrawn) The dosage form according to claim 34, wherein said dosage form contains from 5 to 500 milligrams of active agent.
36. (Withdrawn) The dosage form according to claim 34, wherein said dosage form is

a hard-gelatin capsule.

37. (Withdrawn) The dosage form according to claim 34, wherein said dosage form is a tablet.
38. (Withdrawn) The dosage form according to claim 34, wherein said dosage form is free of lipid or oil solvent.
39. (Withdrawn) A method of treating a disorder in a subject in need thereof, comprising orally administering to said subject an oral dosage form according to claim 34 in a pharmaceutically acceptable amount.
40. (Withdrawn) The method according to claim 39, wherein said oral dosage form is administered to said subject under fed conditions.
41. (Withdrawn) A method according to claim 39, wherein said oral dosage form is administered to said subject under fasted conditions.
42. (Previously presented) The method according to claim 1, wherein the water-insoluble azole antifungal active agent is ketoconazole.